CAYUSE SUPPLEMENTAL FORM (Version 4.1):
ALL SECTIONS MUST BE COMPLETED AT THE TIME OF ROUTING FOR NEW OR COMPETING RENEWAL APPLICATIONS

To ensure regulatory and institutional approval, please complete the questions below on **ALL** 4 pages.

PI: _____ **Cayuse Proposal Number:** _____

For more information, visit the following websites:
IRB: https://www.einsteinmed.edu/administration/human-research-affairs/
IACUC: https://www.einsteinmed.edu/administration/animal-care-use-committee/
EH&S : https://www.einsteinmed.edu/administration/environmental-health-safety/

Input Applicable EHS #: _____
Input Applicable DOR #: _____

ANIMAL SUBJECTS:
If you answered Yes previously in Cayuse SP to the question, "Does this research involve ANIMAL SUBJECTS?" answer the following:

A. Which species of animal will be used? _____ ; _____
B. Do you have an IACUC- approved Animal Use Protocol that includes the animal experiments and/or animal use activities described in this grant application? Yes ☐ No ☐
    a. If Yes, please provide:
        i. IACUC-approved Animal Use Protocol Number(s): _____ ; _____
        ii. Latest IACUC approval date(s): _____ ; _____
        iii. IACUC Proposal PI Name: _____
    b. If No, please note:
        i. IACUC approval is required prior to start of all work. Grant agencies require proof of IACUC approval to release funds.
        ii. IACUC approval requires that we evaluate concordance between the grant and the protocol. Please contact IACUC at Just-In-Time to immediately start the process.
        iii. If inter-institutional animal work is proposed, an MOU between collaborating PHS- Assured institutions is required.

If animal work conceptualized outside of Einstein and will be performed at Einstein, an MOU without PHS- Assurance will be required.

HUMAN SUBJECTS:
Please indicate if the following apply to this grant:

A. Requires obtaining information or biospecimens through an intervention or interaction with a living individual: Yes ☐ No ☐
B. Using, studying, or analyzing information or biospecimens obtained through interaction or intervention with individuals: Yes ☐ No ☐
C. Obtaining, using, studying, analyzing or generating identifiable private information (including access to PHI or medical records) or identifiable biospecimens (including use of discarded clinical specimens): Yes ☐ No ☐
D. Collection, use, receipt or shipping of embryonic stem cells or fetal tissue: Yes ☐ No ☐

IRB ORGANIZATION:

If Yes is checked to any question under the HUMAN SUBJECTS section above, please answer the following:

A. Is this a single site or multi-site study? Single ☐ Multi-site ☐
B. If this is a single site study, it is occurring at Einstein ☐ Montefiore ☐ Burke ☐
C. Is White Plains Hospital participating in this research? Yes ☐ No ☐
D. Name the site if any other Montefiore Health System institution is participating in this research

_____

E. If it is a multi-site study, is each site using a different IRB (multiple IRB's being used) or are all sites using a single IRB? Multiple ☐ Single ☐
F. If multiple sites are using a Single IRB, *is Einstein serving as the single IRB for all sites*?
Yes ☐ No ☐
   a. If Yes, an IRB Reliance Request form is needed at least 10 business days prior to the grant deadline.
      i. Following review of the request form the Einstein IRB will provide:
         1. Single IRB fees that must be included in the budget as a direct cost item
         2. A Single IRB Letter of Support (LOS) that must be attached in Cayuse SP
      ii. Please contact the Einstein IRB with any single IRB related questions at singleirb@einsteinmed.edu.

G. If multiple sites are using a Single IRB that is NOT the Einstein IRB, *which IRB is being used*?

_____

   a. An IRB Reliance Request form is needed at least 10 business days prior to the grant deadline. The IRB will provide:
      i. A Single IRB LOS agreeing to cede to the designated IRB upon Notice of Award (NOA). The LOS must be attached in Cayuse SP.
   b. Have you included the external IRB's fees in the budget as a direct cost item? These fees must be provided by the designated lead IRB. How much will they bill us?
   c. Please contact the Einstein IRB with any single IRB-related questions at singleirb@einsteinmed.edu.

H. Does the participant population include prisoners? Yes ☐ No ☐
If Yes, you must contact the Office of Human Research Affairs and budget for BRANY.
Does this study involve emergency preparedness? Yes ☐ No ☐
If Yes, you must contact the Office of Human Research Affairs.
Does this study investigate a condition experienced by individuals in an emergency setting where there's no opportunity to obtain consent from each individual's legally authorized representative? Yes ☐ No ☐
If Yes, you must contact the Office of Human Research Affairs. For more information on requirements for planned emergency research involving an exception to informed consent, please refer to the following guidance: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed- consent-requirements/index.html.

RedCAP PORTAL:
Do you plan to use RedCAP resources? Yes ☐ No ☐
If Yes, include $1,000 per research protocol in the budget as a direct cost to the grant in year 1. (If there are multiple protocols associated with this grant, use a multiple of $1,000).

CONFLICT OF INTEREST:
Do all investigators have current (i.e. submitted within the past 6 months) Einstein COI disclosures on file (please email COI@einsteinmed.edu ifunsure)? Yes ☐ No ☐
If No, please submit updated COI disclosures at https://einstein.coiriskmanager.com
Reminder: COI disclosures must be submitted every 6 months to avoid delays in funding. For more information on Einstein's COI disclosure policies, refer to the Comprehensive Conflict of Interest Policy. Please contact COI@einsteinmed.edu with any COI-related questions

MATERIALS FROM OUTSIDEORGANIZATIONS:
Will you need to access materials (specimens, animals, samples, datasets) from outside organizations that are NOT covered under a purchase or procurementagreement? Yes ☐ No ☐
If you answered Yes above, complete the following:

A. If transfer of materials involves human specimens or human datasets, did you submit the requestthrough the *Einstein/Montefiore Research Agreement Request Portal*? Yes ☐ No ☐
B. If Yes, when ☐

For all other transfers of materials (incoming or outgoing), contact the Office of Biotechnology and Business Development for next steps (biotech@einsteinmed.edu)

CLINICAL RESOURCES:
Will this study require recruitment/enrollment/performance of the trial on human subjects at aMontefiore facility? Yes ☐ No ☐
Will clinical interventions or services be performed FOR RESEARCH PURPOSES ONLY at Montefiore, including but not limited to specimen processing by the Pathology Department? Yes ☐ No ☐
If Yes, list full procedure description and CPT code (i.e., MRI Chest w/o & w/dye 71552) below:

Full Procedure Description	CPT Code

If you answered Yes to any question in the CLINICAL RESOURCES section, please add the Office of Clinical Trials (OCT) to the routing chain. *Allow two weeks for review and approval.*

PHARMACY RESOURCES:

A. Will you be using an investigational product, drug, biologic (FDA-approved or non-approved, Standard of Care drug or controlled substance) or a device for drug administration as part ofthe project? Yes ☐ No ☐

B. Will the study require pharmacy involvement (drug procurement, storage, accountability, randomization & blinding / preparation &dispensing)? Yes ☐ No ☐

C. Will the study require pharmacy involvement at multiple sites? Yes ☐ No ☐

D. Are you considering requesting a storage waiver? Yes ☐ No ☐

If you answered Yes to any of the above, pharmacy review of the protocol prior to contract negotiation will be required. Please contact pharmacy and email (see below) your protocol to research pharmacy, at least 2 weeks before the grant deadline or contract negotiations for rates and approval:

- Non-Oncology services: Clemencia Solorzano csolorza@montefiore.org and Mark Sinnet mmcids@montefiore.org
- Oncology services: Roy Browne RBROWNE@montefiore.org and Pragna Patel PPATEL@montefiore.org

BUDGET:

1. If anyone named on the budget is not on Einstein payroll, please explain with a note in Cayuse SP.
2. If anyone named on the budget is on the Montefiore payroll, please include a list of who is on Montefiore payroll and who is on Einstein payroll. Also, include Montefiore ORSP on the routing chain.
3. If a budgeted base salary is materially different from the EPAF amount, please explain this in a note in Cayuse SP.
4. Single IRB fees must be included as direct costs in the budget. Please contact the lead IRB to obtain the exact dollar amount.

DATA MANAGEMENT AND SHARING (DMS) PLAN:

Does your research generate data that must be shared according to the NIH Data Management and Sharing Policy? Yes ☐ No ☐

1. If Yes, attach a document in Cayuse 424 Other Plan (s) section of the PHS 398 form. Name the document as **"Data Management and Sharing Plan."**

   i. ***Effective*** *for applications submitted for* ***due dates on or after October 5, 2023****, NIH will require applicants* ***to specify estimated "DMS cost"*** *details within the* ***"Budget Justification"*** *attachment of the* ***R&R Budget Form*** *or "****Additional Narrative Justification"*** *attachment of the* ***PHS398 Modular Budget Form****, pursuant to the instructions.*

   ii. *While the single cost line item is no longer required,* ***"DMS costs" must be requested in the appropriate cost category****, e.g.* ***personnel****,* ***equipment****,* ***supplies****, and* ***other expenses****, following the instructions for the R&R Budget Form or PHS 398 Modular Budget Form, as applicable.*

   The link to the NIH announcement dated July 31, 2023 can be found **here**.

2. If No, a justification document mentioning the reason not to share the data must be attached in Cayuse 424 Other Plan (s) section of the PHS 398 form. For additional information please click **here.**